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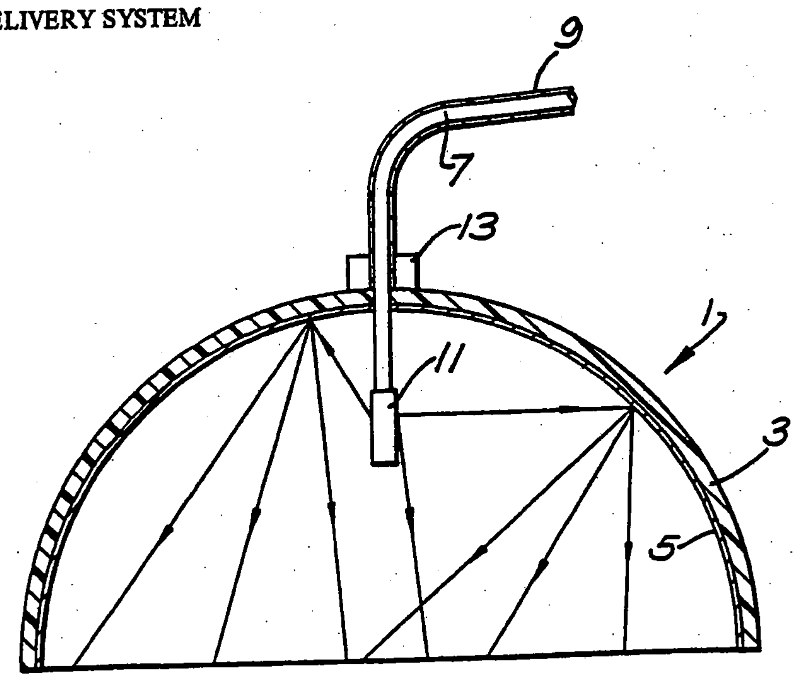

(57) Abstract

A device for uniformly irradiating an area of a surface which accurately defines the area under irradiation and collects lights reflected from the area and scatters it back towards the surface. The device comprises a hemispherical shell (3) whose inside surface is coated with a diffuse reflector and a light source (11) mounted in the shell. The light source may be a diffusing device connected to a laser remote from the shell (3) via an optical fibre (7). In use the shell (3) is placed against the surface under illumination so that the edges of the shell (3) define the area under illumination and the use of the diffusely reflecting surface of the shell prevents any escape of light. A deformable sheet of partly reflective and partly transmissive material may be placed across the open mouth of the hemisphere to cover the target area to increase the uniformity of illumination when the device is used on uneven surfaces. The device is particularly useful in photodynamic therapy.

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LIGHT DELIVERY SYSTEM

This invention relates to an apparatus and method for illuminating an area of an object and in particular to a device in which the total amount of luminant energy delivered to the area can be accurately determined. It is particularly applicable to medical treatment techniques which rely on the illumination of body tissue in order to achieve desired effects e.g. photodynamic therapy and bio-stimulation.

It has been found that certain types of cancer including skin cancer and breast cancer can be treated successfully using a technique known as photodynamic therapy or PDT. In this technique a photosensitizing agent, usually haematoporphyrin derivative (HpD) is administered to the patient and this agent concentrates in the cancerous tissue. It is thought that the agent concentrates in the tumour because it leaks out of the vasculature in the tumour into the surrounding tumour tissue. The lymphatic system within the tumour is not as efficient at removing the HpD as is the lymphatic system in the rest of the body and so for a certain time period there is proportionately more HpD in the tumour than in the rest of the body. At some point in that time period the area of the body with the tumour is irradiated with laser light having wavelength of about 630

nm from an argon dye laser. The effect of the laser light on the HpD is to cause oxygen radicals to be released which destroy the surrounding tumour tissue. In the case of breast cancer the illumination stage of the treatment is usually given twenty-four to seventy-two hours after administration of the HpD agent, though with skin cancer, laser treatment can be delivered up to three or four weeks after the administration of the HpD.

Conventionally the treatment area has been illuminated using laser light directed down an optical fibre, the tip of the fibre being moved over the treatment area. One problem with this method is that the illumination consists of an intense centre spot with the intensity falling away gradually from the centre of the spot. This means that it is difficult to give an even dosage of light to a large area. Furthermore, it is very easy to apply too much light to some areas. In order to attempt to alleviate this problem it has been proposed to deliver the light using an optical fibre bundle with micro-lenses on the end of each fibre or diffusers in the light path to give a broader, more even, illumination area. Another proposal is to control the intensity profile of the beam emerging from an optical fibre by interposing an oblique glass plate between the laser and the optical fibre.

A further problem, which also occurs with the

improved techniques mentioned above, is, however, that since the surface of the body being illuminated is to some extent reflective, it is difficult to determine exactly how much light is absorbed to act on the HpD. The reflectivity of different parts of the treatment area may vary and so even dosage estimates based on an estimated or measured reflectivity are not particularly good. A typical dosage estimate with one of the techniques above was that 30-400 J/cm^2 was delivered to the patient. It can be seen that the upper limit of the range is over ten times the lower limit and this is unsatisfactory both from the point of view of that treatment and for statistically processing the results from many treatments to try to improve the technique.

It has also been proposed to use laser light in other medical treatments, e.g. bio-stimulation in which tissue is irradiated with low power laser light. It has been suggested that this irradiation has certain beneficial effects and has been used to speed-up the healing of wounds, as a beauty treatment and in physiotherapy. Laser illumination has also been used in the treatment of vascular abnormalities such as port wine stain and the removal of tattoos. Other types of light have also been used, for instance, infra red or ultra violet for treating various conditions e.g. the treatment of skin disorders e.g. psoriasis. In some of these agents which render the skin

sensitive to the particular light being used have been administered to the patient. However, similar problems with achieving a uniform illumination and calculating the amount of light delivered to the surface have been found.

The present invention provides a device to deliver a defined quantity of light to a surface comprising a light source for illuminating the surface and means for scattering light reflected from the surface so that it can be directed back onto the surface. Preferably the scattering means are adapted to provide a substantially uniform illumination of the surface.

In more detail the present invention provides apparatus for illuminating an area of an object, comprising a delivery device including a light source for illuminating the area and a concave diffusely reflecting surface, wherein the diffuse reflecting surface is adapted to define the area to be illuminated when the device is held in contact with the object and to collect light reflected from the surface of the object and scatter it back towards the area.

Preferably the light source, which conveniently is the tip of an optical fibre, is arranged to illuminate the diffusely reflective surface so that light from the light source is reflected towards the treatment area. This can be achieved by diffusing the light with, for example, a ceramic reflector or possibly a p.t.f.e. or etched diffuser on the

optical fibre.

The present invention also provides a method of illuminating an area of an object comprising the steps of:

illuminating the area of the object with light from a light source illuminating a concave diffusely reflective surface maintained confronting the area,

positioning the diffusely reflecting surface with its edges in contact with the object so that it collects light reflected from the surface of the object and scatters it back towards the area and so that the edges of the concave diffusely reflecting surface define the area being illuminated.

The light used may be laser light as in the conventional PDT techniques or may be non-coherent light for some applications. The diffusely reflective surface may be the inner, concave surface of a part-spherical,e.g. hemispherical, shell-like structure with the optical fibre and diffusing device attached in its top. In use, the shell is held with its edges in contact with the object under illumination so that any light reflected off the illuminated area is collected and scattered back thereto by the diffusely reflective surface. A reflectivity of 99% can be achieved by coating the concave surface with reflective paint, or any suitable highly reflective coating, e.g. a ceramic.

If the area to be illuminated is smaller than the base area of the hemisphere then parts of the area which do not require illumination can be masked with a highly reflective surface. This means that light striking the reflective surface is not lost but is reflected back towards the diffusely reflective surface and eventually onto the area to be illuminated.

It will be appreciated that with the present invention the amount of light delivered to the treatment area can be accurately determined since none of the light delivered to the area is allowed to escape. This is because almost all of the light reflected from the illuminated area is scattered back towards it by the diffuse reflective surface and since the reflective surface is held in contact with the object, no light can escape under the edges. Furthermore, the use of a diffusing device on the end of the optical fibre delivering the laser light and the use of the diffusely reflective surface mean that the intensity of the illumination is substantially uniform over the whole of the treatment area.

The invention also has benefits for the safety of the operator and, if it is being used in medical treatment, for the patient, as once the reflective surface is in contact with the body the laser system is closed and there is very little risk of accidental injury to the operator or

to the patient caused by escaping laser light. It is possible to arrange for the laser or other light source only to be switched on when the reflective surface is placed in contact with the body - e.g. by a pressure sensitive or temperature sensitive switch or by some other switching means.

If desired the target to be illuminated may be treated with an agent to absorb the light. e.g. a photodegradable or photocensitizing agent. For example where the invention is to be used in photodynamic therapy, e.g. for the treatment of cancer, then a suitable agent which might be preferentially absorbed by certain cells e.g. cancerous cells, e.g. HpD can be administered to the patient some hours before the laser treatment. An accurate amount of light can then be delivered to the treatment area and this allows the operator to calculate more accurately what depth of tissue may be destroyed. This not only allows better treatment of an individual patient but also allows a better correlation of results to treatment conditions and so the best conditions for the treatment of the cancer and different types of cancer may be determined more easily.

The invention is also useful for the treatment of port wine stains, homeopathic processes and bio-stimulation where the fact that the illumination is uniform and defined allow better control of the treatment process.

The invention has been described above in relation to use in medical treatment, e.g. for photodynamic therapy. It is, however, useful in any process where it is desirable to uniformly illuminate an area and to avoid loosing light by reflection from that area. Thus the device could be used in industrial processes for manufacture e.g. for curing substances e.g. plastic resin composites or for optical processes in the manufacture of electronic devices e.g. microchips. In such processes the fact that no light escapes and that a well defined area is illuminated mean that the process can be run economically. Clearly for such processes types of electromagnetic radiation other than optical laser light might be appropriate.

The device may also be useful for promoting biological growth of animals or particularly plants, where again the fact that the illumination is accurately defined and no radiation is allowed to escape can improve the efficiency and economy of the process.

The shape of the reflective surface is not thought to be particularly critical, the preferred embodiment in this specification uses a hemisphere but other concave shapes can be used.

The size of shell is chosen to be close to the size of the area to be illuminated.

A typical size of shell used for medical purposes

would be a few inches in diameter, but larger or smaller shells, e.g. large enough to cover the complete pelvic area, may also be used where appropriate. It is also possible for the reflective surface to be formed on a flexible member so that it can be shaped to match the shape of the area to be treated. These allow the operator to avoid treating areas which do not need treatment.

As an alternative to using a diffusing device on the end of the optical fibre, the fibre may be mounted to direct light onto a diffuse reflector, made from, e.g. a reflective ceramic, mounted in front of the diffusely reflective surface to reflect the light back onto it.

The apparatus may further comprise a deformable sheet of material across the open end of the concave surface, e.g. a sheet of white rubber or synthetic rubber, and which has a high reflectivity, appreciable transmission and low-absorption. The absorption should be low enough to prevent undesirable light loss, e.g. about 1%, and the transmission high enough to allow sufficient illumination of the target surface. For medical applications about 9% is acceptable. The reflectivity should be, for such applications, about 90%.

The invention will be further described by way of non-limitative example with reference to the accompanying drawings which:-

Figure 1 is a cross-sectional view of one embodiment of the invention;

Figure 2 is a partially cutaway view of the embodiment of Fig 1 in use;

Figure 3 is a schematic view of a second embodiment of the invention in use;

Figure 4 shows a third embodiment of the present invention: and

Figure 5 shows a fourth embodiment of the invention

As can be seen by Fig 1 the apparatus comprises a light delivery device 1 which consists of a hemispherical relatively rigid, plastics shell 3 whose inside, concave surface is coated with a reflective coating 5. The coating is a reflective paint or ceramic which provides a diffuse reflective surface. It is possible to achieve a reflectivity as high as 99% or more with such a coating. The shell, intended for medical use in PDT is about 5-15cm in diameter and about 1-2mm thick.

Laser light is supplied to the device along an optical fibre 7, which may be a single fibre or a bundle of fibres. In this embodiment the fibres are teflon coated and retained within a p.t.f.e. sheath 9. The fibres terminate at a diffusing element 11, which is in this embodiment a p.t.f.e. cylinder or, alternatively, a ceramic or etched fibre diffuser (formed by exposure to hydrofluoric acid)

mounted in the hemispherical shell. The fibre is connected to the shell by a two-part block 13 having a bore down the centre through which the fibre and sheath pass. The fibre is trapped in an interference fit between the two parts of the block 13. In the illustrated embodiment the diffuser 11 is positioned about 2cm below the top of the shell. Light transmitted down the fibre passes into the diffuser 11 and is emitted from the end of the diffuser in a number of directions. Some light will be transmitted directly to the treatment surface, but some light will also be transmitted towards the diffusely reflective surface 5. Various light paths are shown in the diagram. Light striking the diffusely reflective surface will be scattered therefrom, partly towards the treatment area and part towards opposing regions of the reflector. It will be appreciated, therefore, that a fairly uniform illumination is achieved within the region defined by the edges of the reflective shell.

Although not shown in the diagram, the shell may be provided with a sensor and switch so that the laser supplying light to the optical fibre 9 is only switched on when the shell is pressed into contact with the surface which is to be illuminated. This results in less chance of the patient or operator being accidentally exposed to laser light and thus improves the safety of the apparatus.

In Fig. 2 the device is shown schematically in use on part of a patient 15. This shows the device used in a situation where the area 17 which is to be illuminated is smaller than the base area of the reflector. The parts of skin which would undesirably be exposed to the light have therefore been masked using a reflective tape 19, for example, aluminium tape. This means that light supplied to the delivery device 1 which misses the exposed treatment area and hits the tape is reflected back up to the diffusely reflective surface and scattered back towards the treatment area.

Figure 3 shows a second embodiment of the invention in use. In this embodiment the reflective shell 22 is formed from a flexible plastics material so that it may be deformed to cover a desired treatment area more accurately. A further feature of this embodiment, which can also be used in the other embodiments of the invention, is that light is supplied to the device by several optical fibres 27 each connected to a diffusing device 11 and spaced over the surface of the shell. This enables a greater amount of light to be delivered per unit time if necessary and helps in maintaining a substantially uniform light distribution particularly in the case where the shell is deformed.

The above embodiments have been described as being supplied with laser light by an optical fibre. However, the

invention is also usable in other applications in which e.g. ultra violet or infra red light or any electromagnetic wave radiation are used. In such applications the light may be delivered to the delivery device using a light guide e.g. liquid or fibre light guide or other types of radiation guides or the light source may be mounted in or on the shell.

Figure 4 shows schematically a third embodiment of the invention in which light delivered to the device by an optical fibre 9 is directed onto a reflector 30 in this case spherical, though other shapes may be used, which reflects light back upon to the diffusely reflective surface which, in turn, scatters it onto the treatment area. The reflector 30, which may be a highly reflective ceramic, is mounted on the shell 1 by a mounting 32.

Figure 5 shows disgrammatically a fourth embodiment of the invention which uses a reflector 1 and light delivery system 9 and 30 as in the previous embodiments, but also includes a deformable partly reflective partly transmissive sheet 50 across the open end of the reflector which, in use, covers the target area. The sheet 50 may be a sheet of white rubber or synthetic rubber and has a high reflectance preferably greater than 17% and more preferably still greater than 77% , very low absorttion preferably less than 5% and appreciable transmission. Typical values which have

been effective in practice are, for instance, 90% reflection, 9% transmission and 1% absorption. This sheet 50 is particularly useful when the device is used to illuminate an uneven surface as it conforms or partly confirms to that surface and improves the uniformity of the light delivered to the target.

With the invention it is possible to calculate the amount of light supplied to the treatment area much more accurately than with the prior art devices. This is because substantially all of the light supplied to the device is eventually absorbed by the treatment surface. None is allowed to escape - because the reflector shell is placed in contact with the object being illuminated and any light reflected from the treatment surface is eventually scattered back by the diffuse reflector towards the treatment surface. Furthermore, the fact, that virtually none of the light supplied to the device is allowed to escape means that the device is particularly safe to use.

While the invention has been described in relation to the medical treatments, as discussed above it is applicable wherever it is required to deliver an accurate and uniform irradiation to a surface, or to substantially reduce the amount of light lost from a system, or to define the area to which radiation should be delivered. The effect of this device in minimizing losses has benefits in that for

a given total energy absorption requirement for a given power output of the radiation source, less time will be needed to bring about that effect.

CLAIMS

1. Apparatus to deliver a defined quantity of light to a surface comprising a light source for illuminating the surface and means for scattering light reflected from the surface so that it can be directed back onto the surface.

2. Apparatus according to claim 1 wherein the scattering means are adapted to provide a substantially uniform illumination of the surface.

3. Apparatus for illuminating an area of an object, comprising a delivery device including a light source for illuminating the area and a concave diffusely reflecting surface, wherein the diffusely reflective surface is adapted to define the area to be illuminated when the device is held in contact with the object and to collect light reflected from the surface of the object and scatter it back towards the area.

4. Apparatus according to claim 3 wherein the light source is adapted to illuminate the diffusely reflective surface so that light from the light source is scattered towards the area of the object.

5. Apparatus according to claim 3 or 4 wherein the light source is a source of laser light.

6. Apparatus according to claim 3,4 or 5 wherein

the light source includes an element for distributing the light onto the reflecting surface.

7. Apparatus according to claim 6 wherein the element is a diffusely reflecting body

8. Apparatus according to claim 6 wherein the element is a p.t.f.e. cylinder.

9. Apparatus according to any one of the preceding claims wherein the diffusely reflective surface is the concave surface of a shell-like structure, the edges of the shell defining the area to be illuminated when it is held in contact with the object.

10. Apparatus according to claim 9 wherein the concave surface is coated with a reflective ceramic to form the diffusely relective surface.

11. Apparatus according to any one or the claims 3 to 10 further comprising a deformable sheet of material across the open-end of the concave surface, said material having a high light reflectance, appreciable light transmission and low light absorption for the light from said light source.

12. A method of illuminating an area of an object comprising the steps of:

illuminating the area of the object with light from a light source preferably a laser light source, illuminating a concave diffusely reflective surface maintained

confronting the area,

and positioning the diffusely reflecting surface with its edges in contact with the object so that it collects light reflected from the surface of the object and scatters it back towards the area and so that the edges of the concave diffusely reflecting surface define the area being illuminated.

13. A method according to claim 12 wherein the diffusely reflecting surface is illuminated by light delivered by an optical fibre to a diffuser, e.g. of ceramic or a p.t.f.e. cylinder,

14. A method according to claim 12 or 13 wherein the area is provided of with a degradable agent for absorbing the light.

15. A method according to claim 12,13 or 14, wherein light from the concave surface is transmitted through a deformable sheet covering the surface, the sheet having properties of high light reflectance, appreciable light transmission and low light absorption.

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FIG. 1

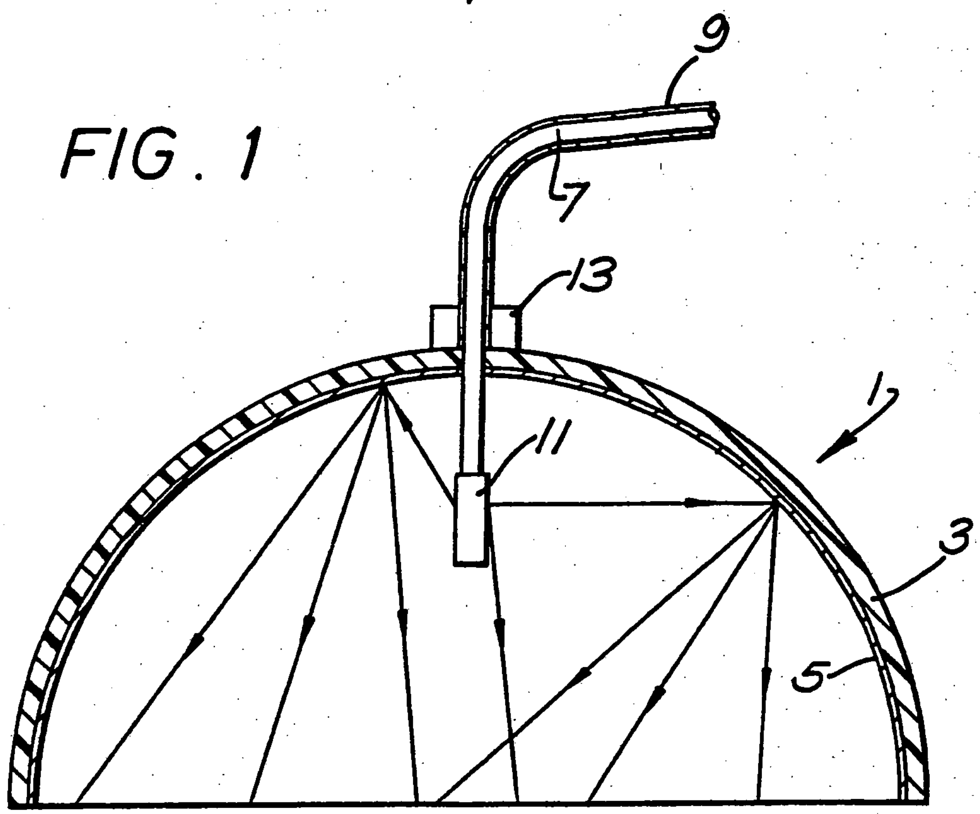


FIG. 2

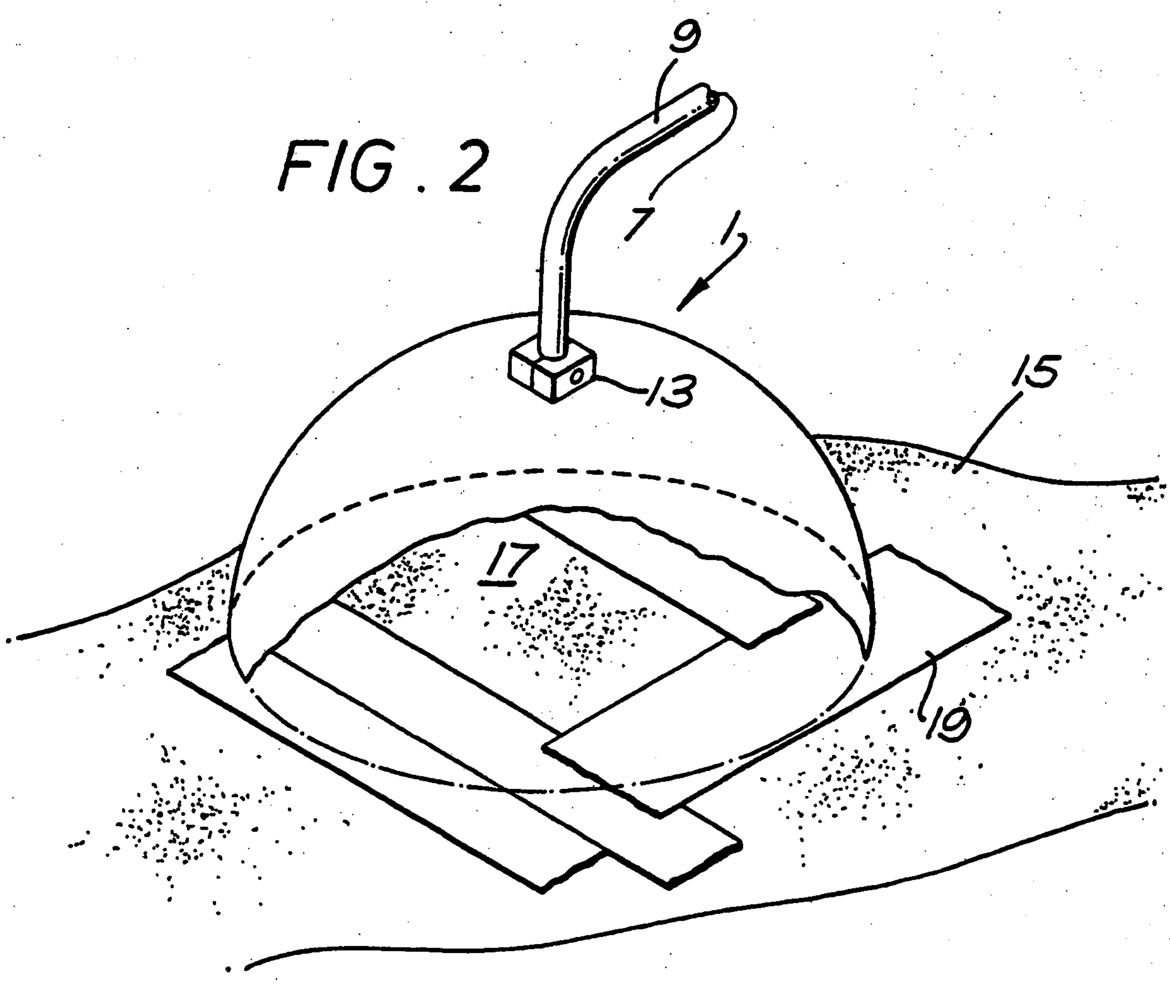


FIG. 3

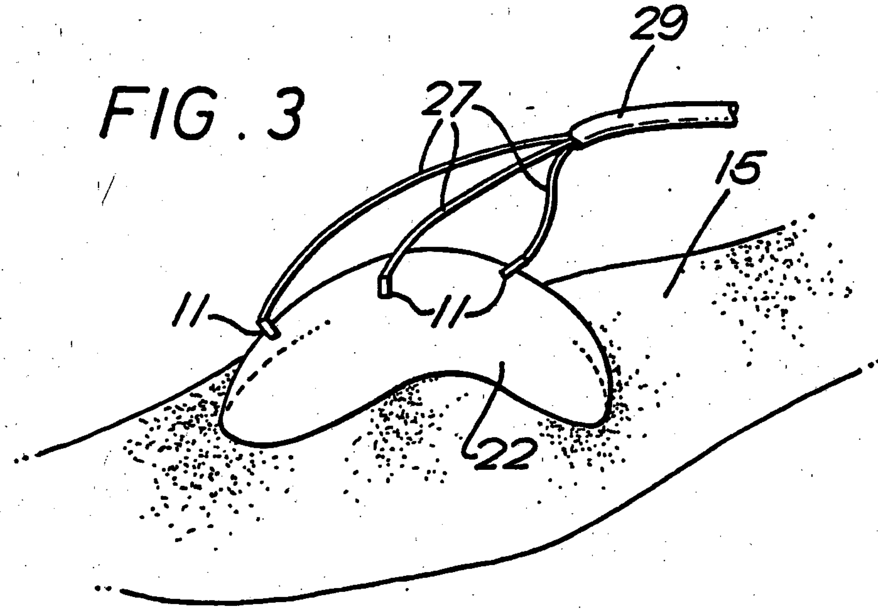


FIG. 4

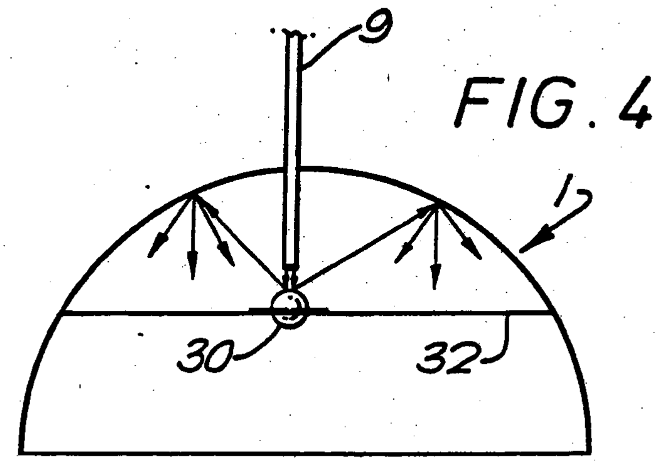
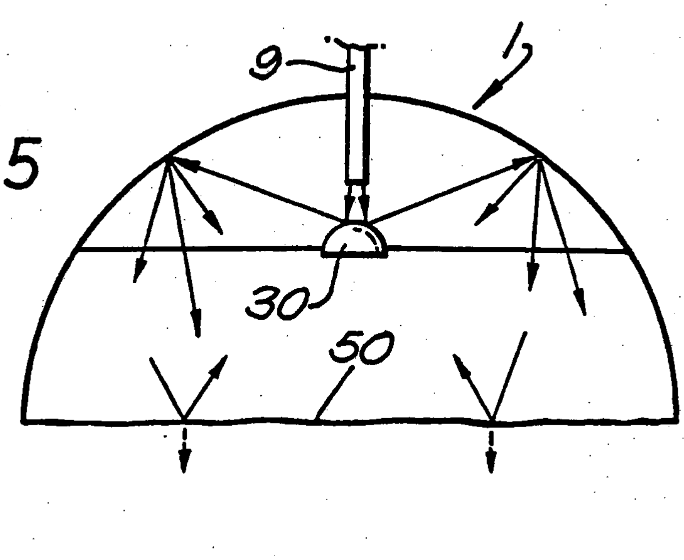


FIG. 5



INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 89/00796

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC^5: A 61 N 5/06

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC^5	A 61 N, A 61 B

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category [*]	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X	FR, A, 2591902 (COLLIN) 26 June 1987, see page 3, lines 28-32; page 6, lines 7-11; figure 4 --	1-5,9,12
X	DE, A, 3300517 (MERSMANN) 26 July 1984, see page 9, lines 12-20; page 52, lines 32-37; page 99, lines 9-33; figures 93-96 ----	1-10,12

* Special categories of cited documents: [10]

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"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
18th October 1989	13 NOV 1989
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	T.K. WILLIS

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. GB 8900796

SA 30105

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
The members are as contained in the European Patent Office EDP file on 08/11/89
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR-A- 2591902	26-06-87	None	
DE-A- 3300517	26-07-84	None	

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82